

**REMARKS**

**I. Amendments**

Claims 2 and 27 have been amended to correct a minor typographical errors. New claims 28 and 29 have been added, and are believed to be supported by the original claims, and at page 17, lines 11-17 of the present specification.

No new matter is believed to have been added. Claims 1-24 and 27-29 are active.

**II. Rejections Under 35 U.S.C. §103**

The Examiner has rejected the claims as obvious in view of *Engelmann (Gamete Research*, 19:151-159 (1988)) and *Rylatt* (WO 2004/101117). Applicants respectfully disagree.

The claimed invention is a method for separating a sperm type from a sperm population, by subjecting the sperm to an electric potential which causes selected types of sperm cells to diffuse “through an ion-permeable barrier.” As discussed in the present specification, the claimed process is not only capable of separating a sperm type from a sperm population, but the resulting separated sperm type is “substantially unchanged” by the process. For example, sperm separated by the claimed process maintain their fertilizing potential and other properties such as motility. Applicants note in particular that after electrophoresis for 5 minutes using the claimed process, mean sperm motility is only slightly affected, and after 3.5 hours post-treatment, motility recovers to essentially the level observed for untreated sperm samples.<sup>1</sup>

*Engelmann* describes a free-flow electrophoresis process for separating human sperm. As noted by the Examiner, “the free-flow electrophoresis of ENGELMANN does not provide for a membrane, but rather a flow system of substantially laminar flow perpendicular to the electrical field.” The Examiner proposes “adding a membrane to the separation device of ENGELMANN” in order to provide the claimed method. However, adding membranes to a free-flow electrophoresis apparatus would destroy the laminar flow which is essential to the mechanism of separation of a free-flow electrophoresis separation process, thereby rendering a

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<sup>1</sup> e.g., present specification, page 17, and Figure 6.

device modified in this manner inoperable. Accordingly, Applicants respectfully submit that it would not be obvious to modify the process of *Engelmann* in the manner proposed by the Examiner. *See* MPEP §2143.01 (V).

Furthermore, *Engelmann* teaches that the motility of sperm separated by free-flow electrophoresis is “greatly reduced”, for example “in the range between 5% and 10%” or 10% and 20%, depending upon the sperm fraction selected.<sup>2</sup> In other words, *Engelmann* teaches that separation of sperm by electrophoresis substantially affects the motility of separated sperm. In contrast, as noted above the claimed electrophoresis method produces separated sperm which are “substantially unchanged” – *e.g.*, have essentially unchanged motility 3.5 hours after electrophoresis. Thus, the claimed method provides substantially improved results compared to the closest prior art process (*i.e.*, *Engelmann*).

Accordingly, Applicants respectfully submit that the substantially improved results (e.g., sperm motility, etc.) provided by the claimed process compared to the cited prior art process reasonably rebuts any allegation of obviousness by the Examiner based on *Engelmann*. Applicants therefore request that the rejection be withdrawn.

### III. New Claims 28 and 29

The process of new claim 28 provides separated sperm which “3.5 hours after treatment” have a “motility value which is  $94 \pm 10\%$  of the motility value of untreated sperm”, and new claim 29 provides a process in which “at least about 50%” of the separated sperm remain “substantially unchanged after separation.”

In direct contrast, *Engelmann* states that “[p]rogressive motility of the separated spermatozoa was greatly reduced in each fraction. Motility of the slower migrating X spermatozoa was in the range between 5% and 10%. ... The estimated motility [of the Y spermatozoa] was between 10% and 20%” (underline added). Thus, *Engelmann* clearly states that free-flow electrophoresis provides separated sperm with quite *low* motility values (well

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<sup>2</sup> *Engelmann*, page 156

outside motility range of claim 28), and thus nearly all of the sperm are substantially *changed* after separation (*i.e.*, in contrast to the process of new claim 29 in which at least 50% of the sperm are “substantially unchanged”). Thus, compared to the closest prior art sperm separation process (*i.e.*, *Englemann*), the processes of new claims 28 and 29 provide separated sperm with substantially superior properties.

In addition, since *Englemann* teaches that free-flow electrophoresis substantially affects the motility of sperm cells after separation, Applicants respectfully submit that one skilled in the art would expect that other electrophoresis methods, particularly electrophoresis methods in which sperm cells diffuse through ion-permeable membranes, would likely cause more damage to the separated sperm cells, as they would experience both an electric field and contact with the pores of the ion-permeable membrane. However, as discussed above, Applicants have found that the claimed membrane-based electrophoresis process actually provides separated sperm with less damage than the method of *Englemann*. Applicants submit that the superior results provided by the processes of new claims 28 and 29 reasonably rebut any allegation of obviousness by the Examiner based on *Englemann*. Applicants therefore submit that new claims 28 and 29 are patentable in view of *Englemann* and *Rylatt*.

Finally, as discussed above, *Englemann* fails to teach or suggest processes which provide separated sperm having the limitations of new claims 28 and 29. *Rylatt* fails to even mention sperm separation. Thus, the combined references necessarily fail to teach or suggest all of the limitations of new claims 28 and 29, and therefore fail to support *prima facie* obviousness. For this additional reason, Applicants submit that new claims 28 and 29 are patentable in view of *Englemann* and *Rylatt*.

Applicants believe the application is now in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to contact the undersigned.

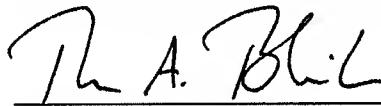
Entry and consideration of the foregoing amendments is respectfully requested.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

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